

REMARKS

Claims 1-32 are pending and under consideration.

In items 2 and 3 of the Office Action, the Examiner raises provisional obviousness type double patenting rejections based on U.S. Application No. 09/826,418. The Examiner is requested to hold the requirement for a terminal disclaimer in abeyance until at least one of the two applications is indicated as otherwise being in condition for allowance.

In item 6 of the Office Action, claims 1, 4-7, 15 and 18-21 are rejected under 35 U.S.C. § 103(a) as being obvious over U.S. Patent No. 5,749,203 to McGowan, Jr. ("the '203 patent").

While the '203 patent does relate to a similar technology as the present application, it appears that the Examiner has overlooked key points, both in the '203 patent and the claims of the present application. Independent claim 1 and several other claims recite that the medical article is preheated in a pretreatment area. The Examiner has apparently noted column 1, lines 37-45 of the '203 patent. This portion of the reference describes that for a related art process, a preconditioning phase was provided to elevate the temperature and relative humidity of the palletized articles. Although the '203 patent recognizes preheating, the paragraph bridging columns 2 and 3 indicates that one drawback associated with the related art process is the length of time required for the process.

Nowhere does the '203 patent suggest that preheating may be used with the form-fill-and-seal machine 14. For example, at column 9, lines 23 and 24, the '203 patent indicates that the article dispensing station 410 properly places the articles 414 to be sterilized in the formed bottom web 412. There is no mention of any preheating room or any preconditioning is performed. The process starts at the article dispersing station. The Examiner should not presume that preheating or pretreatment may be done for the form-fill-and-seal process.

In addition to the confusion with regard to the pretreatment area, the Examiner cites other portions of the '203 patent which indicate that there could be some confusion. For example, the Examiner cites column 2, lines 42-58 to support his position that no moisture is supplied to the medical articles at the sterilization-sealing station. The Examiner is again referred to the paragraph bridging columns 2 and 3 of the '203 patent. This portion of the reference does not relate to the claimed device or the form-fill-and-seal device of the '203 patent.

| Each of the independent claims includes a recitation indicating that sterilization occurs

and then the first and second webs are sealed together. For example, independent claim 15 recites "after sterilizing the medical article, sealing the first web to the second web."

Throughout the '203 patent it is described that sterilization occurs after the first and second webs are sealed. For example, at column 12, line 63 through column 13, line 4, the '203 patent indicates that sterility is achieved after about 6 hours of degassing. Column 14, lines 7-13 indicate that sterility is achieved at between about 7.5 hours to about 9.4 hours of degassing. Column 18, lines 50-52 indicate that sterility is generally achieved after degassing for about 22 hours from the introduction of ethylene oxide into the housing.

In addition to the above, the '203 patent contains numerous tables which show that sterility does not occur until after sufficient degassing. The test results in table II, for example, show that package number 3 passes one sterility test but fails two other sterility tests. There is a lengthy discussion with regard to the degassing conditions that must be satisfied before sterility will occur.

In the '203 patent, degassing occurs after the form-fill-and-seal chamber and after the first and second webs are sealed. Column 4, lines 17-21 indicate that "[t]he closed housing is conveyed to a degassing area" (emphasis added). Column 4, lines 56-60 indicate that individual housings are case-packed and sent to a degassing area. To form individual housings, the first and second webs must be sealed. Column 11, lines 39-44 indicate that the heat sealer 436 is lowered to seal the top and bottom webs 416 and 412. Referring to column 11, lines 49-56, after the heat sealer 436 is raised, the closed housing is sent for degassing. The '203 patent is clear that the webs are sealed before degassing. In view of the above discussed claim limitations, which were not disclosed in or suggested by the '203 patent, it is submitted that the rejection should be withdrawn.

Claims 2, 3, 8-14, 16, 17 and 22-32 are rejected under 35 U.S.C. § 103(a) as being obvious over the '203 patent in view of a Multivac Packaging Machines reference. Claims 2, 3, 16 and 17 depend directly or indirectly on claim 1 or claim 15, which are discussed above. With regard to independent claim 8, this claim recites a sterilization-sealing station where the first web and the second web, with the medical article loaded into the housing are sterilized and then, the first and second webs are sealed together. Independent claim 22 recites after sterilizing the medical article, sealing the first web to the second web, with the medical article located in the housing and between the first and second web. As discussed above, the '203 patent does not suggest sealing the first web to the second web after sterilizing the medical

article.

The Multivac Packaging Machines reference is only cited for including gas injection pins in a form, fill and seal device. The Multivac Packaging Machines reference does not compensate for the deficiencies discussed above with regard to the '203 patent. Specifically, the Multivac Packaging Machines reference does not suggest sealing the first web to the second web after sterilizing the medical article. Accordingly, independent claims 8 and 22 and the claims dependent thereon patentably distinguish over the '203 patent and the Multivac Packaging Machines reference, taken alone or in any proper combination.

There being no further outstanding objections or rejections, it is submitted that the application is in condition for allowance, except for possible provisional obviousness type double patenting rejections. An early action indicating allowable subject matter is respectfully requested.

If there are any formal matters remaining after this response, the Examiner is requested to telephone the undersigned to attend to these matters.

If there are any additional fees associated with filing of this Amendment, please charge the same to our Deposit Account No. 19-3935.

Respectfully submitted,

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